Remarks

Claim 3 has been cancelled without prejudice to or disclaimer of the subject matter contained therein. Claims 1 and 2 have been amended to clarify the issues remaining in this application, for example, referencing the explicit definition of "complement" on page 16, lines 15-19 of the specification. No new matter enters by way of these amendments.

The Decision suggests that the phrase "its complement," as used in the claims on appeal prior to this amendment, was ambiguous with respect to whether this included a nucleic acid molecule that exhibits "complete complementarity" to another nucleic acid molecule or whether departures from complete complementarity were permissible. *See* Decision at page 3. In response, Applicants have amended the claims to read ". . . the complete complement of SEQ ID No: 1" to indicate that the word "complement," as used in the claims, envisions the explicit definition in the specification, *i.e.,* "[a] nucleic acid molecule is said to be the 'complement' of another nucleic acid molecule if they exhibit complete complementarity. As used herein, molecules are said to exhibit 'complete complementarity' when every nucleotide of one of the molecules is complementary to a nucleotide of the other." Specification at page 16, lines 15-19. Therefore, as used in the presently pending claims, "complement" refers to a nucleic acid molecule having complete complementarity to a nucleic acid molecule of SEQ ID No: 1.

The remaining claims stand rejected under 35 U.S.C. § 101 and 112, first paragraph. The Board of Patent Appeals and Interferences ("Board") in its Decision affirmed the rejection of claims 1-3 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, for lack of enablement. The Board did not reach the merits of the rejection of claims 1 and 3 under 35 U.S.C. § 112, first paragraph, for lack of written description. The Board further rendered a new ground of rejection under 37 C.F.R. § 1.196(b) of claims 1-3 under 35 U.S.C. § 101 because their reasons for concluding that the claims lack patentable utility differ substantially from those advanced by the Examiner. Applicants respectfully traverse all of the rejections of each of the pending claims.

I. The Rejection Under 35 U.S.C. § 101, Utility

The rejection of pending claims 1-2 under 35 U.S.C. § 101 for allegedly lacking either a specific asserted utility or well-established utility was affirmed by the Board. *See* Final Office Action mailed March 22, 2000 (Paper No. 14) ("Final Action"), at page 2, Decision at page 2. Furthermore, because the Board concluded that the claims lacked patentable utility for reasons that "differ substantiality from those advanced by the Examiner," the rejection for lack of utility has been denominated as a new ground of rejection under 37 C.F.R. § 1.196(b).[1] Decision at page 2. Applicants respectfully disagree.

The Decision acknowledges that Applicants have disclosed several specific utilities for the claimed nucleic acid molecules throughout the present specification, which have been additionally cited by the Examiner. *See, e.g.,* Decision at pages 3-4. None of these asserted utilities have been contested by the Board as being inoperable, unbelievable or incapable of being achieved using the claimed nucleic acid molecules. Rather, the Board rests its determination that the present invention lacks utility on the incorrect analysis that "the facts in this case represent the lowest end of the [utility] spectrum, i.e., an insubstantial use." Decision at page 23.

The Decision asserts that there is allegedly a "spectrum" in the biochemical arts for determining whether an invention satisfies the utility requirement of 35 U.S.C. § 101. According to the Decision, the claimed nucleic acid molecules have utility that would "represent the lowest end of the spectrum, i.e., an insubstantial use." Decision at page 23. This type of analysis is improper and has no support in law. The evaluation by the Board of the utility requirement in

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[1] The Decision additionally notes that neither the Applicants nor the Examiner considered the latest version of the Revised Utility Examination Guidelines, 66 Fed. Reg. 1092 (January 5, 2001) ("Utility Guidelines") in the preparation of Appellant's Brief dated January 31, 2001 ("Appellant's Brief") and the Examiner's Answer mailed August 6, 2001 (Paper No. 24) ("Examiner's Answer"), respectively. *See* Decision at page 13, footnote 4. Applicants note that the Utility Guidelines do not differ substantially from the Revised Utility Examination Guidelines set fort in 64 Fed. Reg. 71440, 71442. Applicants also note that such guidelines are not binding on Applicants. *See Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 964, 63 U.S.P.Q.2d 1609,1613 (Fed. Cir. 2002) ("[t]he Guidelines, like the Manual of Patent Examining Procedure ("MPEP"), are not binding on this court, but may be given judicial notice to the extent they do not conflict with the statute.") Nonetheless, Applicants herein consider the most recent Utility Guidelines in the present analysis.

the context of an asserted "utility spectrum" misconstrues the requirements of 35 U.S.C. § 101, "devising out of whole cloth novel propositions of law". *Paulik v. Rizkalla,* 760 F.2d 1270, 1276, 226 U.S.P.Q. 224, 228-229 (Fed. Cir. 1985) (Rich, J., concurring).

It is undisputed in patent jurisprudence that "[t]he basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility." *Brenner v. Manson,* 383 U.S. 519, 534, 86 S.Ct. 1033, 1042, 148 U.S.P.Q. 689, 695 (1966). It is further well-settled law that substantial utility is shown "where specific benefit exists in currently available form". *Brenner,* 383 U.S. at 543-535. This benefit has never been evaluated in the context of a spectrum, as the Board asserts. Rather, practical utility for an invention turns on a factual analysis of the disclosure of the specification to determine simply if there is a benefit that is specific and currently available. *Cross v. Iizuka,* 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). *Brenner* says that a future benefit "which either has no known use or is useful only in the sense that it may be an object of scientific research" is not substantial, but *Brenner* does not suggest that a benefit that is known and currently available is, or could be, insubstantial. *Brenner,* 383 U.S. at 534-535.

The Decision asserts that "[r]ather than setting a de minimis standard, § 101 requires a utility that is 'substantial', i.e., one that provides a specific benefit in currently available form." Decision at page 20 (emphasis in original). While Applicants agree that the claimed invention provides a specific benefit in currently available form, the Board's suggestion that this benefit is evaluated within some asserted "spectrum" of utility institutes a new standard of utility that is not supported by the current law. To the contrary, it is well-settled that "[t]he threshold of utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.,* 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson,* 383 U.S. at 534. Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983)

("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The courts have expressed a test for utility that hinges on whether an invention provides an "identifiable benefit." *Juicy Whip,* 185 F.3d at 1366, *citing Brenner v. Manson*, 383 U.S. at 534. For analytical purposes, the requirement for an "identifiable benefit" may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or substantial benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be "totally incapable of achieving a useful result," *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

In the present application, Applicants have asserted, for example, that the claimed nucleic acid molecules are useful in determining the presence or absence of a polymorphism in a plant population and, in particular, in a soybean plant population.[2] Specification at page 28, line 3, through page 35, line 16; Appellant's Brief at pages 11-15. The specification also describes that polymorphisms, in general, are useful in analyzing whether or not a plant population contains a mutation that may affect the pattern or expression of an mRNA or protein expressed by those plants. Specification at page 27, line 9, through page 28, line 6. Furthermore, Dr. Wiegand submitted testimony that "[t]he detection of polymorphisms is useful for genetic analysis and the development of genetic maps to tag important agronomic traits such as tolerance to abiotic stress and pathogen resistance." Declaration at ¶ 20. In short, the invention provides a known, currently available benefit.

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[2] This utility is well documented with the claimed nucleic acid molecules and has been confirmed by the Declaration of Dr. Wiegand under 37 C.F.R. § 1.132, dated August 17, 2000 ("Declaration"). Furthermore, no evidence has been submitted either by the Examiner or the Board to discredit the assertion of this utility for SEQ ID No. 1.

Moreover, it is well known that EST molecules are commonly used as molecular markers (*e.g.*, from the identification of restriction length fragment polymorphisms (RLFP)) and as genetic markers, for example, to identify a gene locus, trait locus, or QTL. *See* Declaration at ¶ 12. The use of molecular markers is a practical activity in the development of nutritionally enhanced or agriculturally enhanced crops. Such markers are useful in, for example, genetic mapping or linkage analysis, marker-assisted breeding, physical genome mapping, transgenic crop production, crop monitoring diagnostics, and gene identification and isolation. As more markers are identified, genetic maps will become more detailed and it will be easier for plant breeders to breed for particular traits such as disease resistance and crop yield. *See* Applicants' Second Response dated August 22, 2000, at pages 11-12, and articles referenced therein; Appellant's Brief at page 11. In addition, Applicants respectfully point out that the utility of EST molecules is well recognized in the art for these purposes as supported by the references submitted herewith and cited in the accompanying Information Disclosure Statement.[3] Thus, much like the situation in *Nelson,* the nucleic acid molecules of the present invention contribute to an arsenal of tools available to assist plant breeders. *Nelson v. Bowler,* 626 F.2d 853, 856, 206 U.S.P.Q. 881, 883 (C.C.P.A. 1980).[4]

Neither the Board nor the Examiner has presented a *prima facie* case to contradict the truth of this utility or shown that the claimed nucleic acid molecules could not be used to detect the presence or absence of a polymorphism in a population of soybean plants.[5] Instead of

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[3] *See, e.g.,* Foster-Hartnett, *et al.,* "Comparative genomic analysis of sequences sampled from a small region on soybean (Glycine max) molecular linkage group G", *Genome, 45*:634-645 (2002) (disclosing the use of a mere eight DNA markers spanning 10 cm to identify BAC clones); Liebhard *et al.,* "Mapping quantitative physiological traits in apple (*Malus* x *domestica* Borkh)", *Plant Mol. Bio., 52*: 511-526 (2003) (disclosing the utility of 840 molecular markers covering all 17 apple chromosomes for mapping QTLs), both of which are submitted herewith in the accompanying IDS.

[4] In *Nelson* the court concluded "[k]nowledge of the pharmacological activity of any compound is obviously beneficial to the public. It is inherently faster and easier to combat illnesses and alleviate symptoms when the medical profession is armed with an arsenal of chemicals having known pharmacological activities. Since it is crucial to provide researchers with an incentive to disclose pharmacological activities in as many compounds as possible, we conclude that adequate proof of any such activity constitutes a showing of practical utility." *Nelson v. Bowler,* 626 F.2d at 856.

[5] In contrast, Applicants have presented testimony supporting the use of SEQ ID No: 1 to detect polymorphisms and RLFPs. *See, e.g.,* Declaration at ¶¶ 21-23.

successfully challenging this asserted utility for the claimed nucleic acid molecules under the currently accepted legal standard, the Board sidesteps the issue altogether and asserts that while this is a utility, it represents the lowest end of an alleged utility spectrum, *i.e.*, an insubstantial use. *Id.* at page 23.

The Board supported its decision by reference to *In re Ziegler,* 992 F.2d 1197, 1203, 26 U.S.P.Q.2d 1600, 1605 (Fed. Cir. 1993) (in an interference, utility requirement was not satisfied where the applicant disclosed only that solid granules of polypropylene could be pressed into a flexible film with a characteristic infrared spectrum and that the polypropylene was "plastic-like"; no practical use or characteristics for the polypropylene or its film were asserted.) Unlike the situation in *Ziegler*, Applicants have not made a vague assertion of a possible future utility, but rather have stated a *specific* utility of the claimed nucleic acid molecules that exist in currently available form. The claimed nucleic acid molecules have utility by themselves, for example, they can be used to identify a polymorphism (or lack thereof) in a population of soybean plants. This utility does not depend on the ultimate role of a gene or promoter corresponding to the claimed nucleic acid molecules in the development of a plant. Instead, this asserted utility helps to determine information about the plant itself, much like the utility of a screening assay[6] or a gas chromatograph.[7]

The Board also supported its decision by reference to *In re Kirk,* 376 F.2d 936, 553 U.S.P.Q. 48 (C.C.P.A. 1967), where the utility for doing research to discover other uses was held to be insufficient for purposes of Section 101. In contrast, Applicants have asserted the specific

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[6] For example, the screening assay's utility arises from its ability to tell the practitioner if a blood or body fluid sample is infected with a disease organism, or not. *E.g.*, U.S. Patent Nos. 6,153,411 (issued November 28, 2000); 6,140,055 (issued October 31, 2000); and 6,120,776 (issued September 19, 2000).

[7] Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have clear, specific and unquestionable utility (*e.g.*, they are useful in analyzing compounds)." MPEP § 2107 at page 2100-25. For example, gas sampled from crude oil may be analyzed by gas chromatography for the presence or absence of chlorine, which is toxic to catalysts used in gasoline refining even in very low concentrations. The absence of a peak at the molecular weight of chlorine indicates the absence of chlorine in the sample being tested, thereby providing useful information (no chlorine is present, therefore the catalyst will not be destroyed) to the refinery manager. *See, e.g.*, U.S. Patent No. 6,133,740 entitled "Chlorine Specific Gas Chromatographic Detector."

biological properties that make the claimed nucleic acid molecules useful, *e.g.*, the ability to detect the presence or absence of polymorphisms or act as nucleic acid probes or molecular markers via their ability to hybridize to specific sequences of DNA using methods well known in the art. These assertions are not "so general as to be meaningless," nor do they require further experimentation "to determine actual uses--or possible lack of uses-- of the compounds, as well as how to employ them in a useful manner." *In re Kirk*, 376 F.2d at 942. Rather, the asserted utilities are specific utilities that are currently available.

The utilities of an EST molecule are well known in the art and do not need to be specifically called out. *See In re Gaubert,* 524 F.2d 1222, 1224, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) ("a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of s 101 for the entire claimed subject matter unless there is reason for one skilled in the art to question the objective truth of the statement of utility or its scope.") *quoting In re Langer,* 503 F.2d 1380, 1391-92, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974).[8] Moreover, Applicants have asserted, and the Declaration supports, that the claimed nucleic acid molecules are useful to detect a polymorphism in a population of soybean plants. This utility is specific to the claimed nucleic acid molecules and has not been contested by the Board.[9] Rather, to the extent that this utility has been challenged, the Board has already acknowledged that "a given EST may or may not detect a polymorphism in a related organism". Decision at page 24. Thus, any obligation on Applicants' part to prove this asserted utility appears to be moot.

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[8] *See also Cross v. Iizuka,* 753 F.2d at 1044 ("[i]t is axiomatic that an invention cannot be considered 'useful'. . . unless substantial or practical utility for the invention has been discovered and disclosed where such utility would not be obvious."); *In re Jolles,* 628 F.2d 1322, 1326, 206 U.S.P.Q. 885, 890 (C.C.P.A. 1980) ("[p]roof of utility is sufficient if it is convincing to one of ordinary skill in the art.")

[9] The Board additionally challenges the Declaration of Dr. Wiegand with respect to the assertion that the claimed nucleic acid molecules can be used to detect the presence or absence of a polymorphism. The Decision argues (1) "the precise identity of the nucleic acid molecules used in Dr. Weigand's work is unclear," and (2) the Dr. Wiegand does not state in his declaration that result of his experiment using SEQ ID No. 1 provides any significant knowledge. Decision at pages 23-24. This analysis misses the point.

There is no legal support for the Board's assertion that a utility may be useful "to some degree" but could still fail to represent a substantial utility. Decision at page 24. Rather, the courts have held that substantial utility is satisfied where activity, for example, of a composition has been show, even when a specific use has not been established. *See, e.g., Nelson,* 626 F.2d at 856-857 ("tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use.") In the present case, much like the facts in Nelson, the claimed nucleic acid molecules are useful because they allow genetic researchers to more readily determine and breed plants for desired traits. *See Nelson,* 626 F.2d at 857; *Hoffman v. Klaus,* 9 U.S.P.Q.2d 1657 (B.P.A.I. 1988). The standard for proof of utility is that it be sufficiently convincing to one of ordinary skill in the art. *In re Jolles,* 628 F.2d at 1326. Applicants have satisfied this test for utility. No greater proof of the function of SEQ ID No. 1 to identify polymorphisms is required.

Applicants have asserted several substantial utilities in the present application that provide a specific benefit in currently available form, for instance, as markers and probes. These utilities are credible to those of ordinary skill in the art. No greater test need be satisfied. *See In re Brana,* 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995) ("the PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure. . . Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility.") (Citations omitted). In the present case, Applicants have asserted specific, credible, and substantial utilities for the claimed nucleic acid molecules. Furthermore, no evidence has been submitted by either the Board or the Examiner to counter the truth of the statements of these asserted utilities.

In view of the forgoing arguments, the rejection of pending claims 1 and 2 under 35 U.S.C. § 101, cannot stand. Applicants have asserted substantial, specific, and credible utilities in the specification and have supported these assertions in subsequent papers. In contrast, no

evidence has been presented to contradict the assertions of utility in the present application. Thus, reconsideration and withdrawal of this rejection is respectfully requested.

II. The Rejection Under 35 U.S.C. § 112, First Paragraph, Enablement

A. The Claimed Invention is Enabled Because It Has Utility

The Board affirmed the rejection under 35 U.S.C. § 112, first paragraph, for lack of enablement because the claimed nucleic acid molecules allegedly lack utility and therefore one of skill in the art would not know how to use the claimed invention.[10] Decision at page 32.

Applicants believe this rejection is erroneous and has been overcome by the forgoing arguments regarding utility. Applicants further maintain that the Office has not met the burden to sustain the rejection under 35 U.S.C. § 112, first paragraph, for lack of enablement. Thus, reconsideration and withdrawal of this rejection is respectfully requested.

B. The Claimed Invention is Enabled Because One Skilled in the Art Would Know How to Make and Use The Nucleic Acid Molecule of Claim 1

The Decision notes that the Examiner's Answer set forth two rationales for the rejection based on 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. Decision at page 32. The Decision further notes that the "examiner's second position focuses on claims 1 and 3 and their use of the transitional phrases 'comprising' and 'consisting essentially of.' " *Id.* However, the decision does not indicate the Board's position on this rejection. It appears that the Board's position on this rejection, should it be maintained by the Examiner, is that the Examiner is required to state his analysis of this rejection in light of the factors presented in *In re Wands,* 828 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). *See* Decision at pages 6-8.

Applicants respectfully point out that claim 3 has been cancelled in the present amendment and therefore this rejection, should it be maintained, is addressed only to pending

[10] The Board also pointed out that the enablement rejection "is simply a corollary of the finding of lack of utility." Decision at page 32. Thus, the rejection under 35 U.S.C. § 112, first paragraph, for lack of enablement collapses into the utility rejection under 35 U.S.C. § 101.

claim 1. Applicants have already presented their position on this rejection in Appellant's Brief under the analysis of the factors presented in *In re Wands* and herein reiterate and incorporate by reference their arguments regarding this rejection as presented in Appellant's Brief at pages 27 through 36.

Applicants further maintain that the Office has not met the burden to sustain the rejection of claim 1 under 35 U.S.C. § 112, first paragraph, for lack of enablement. Thus, reconsideration and withdrawal of this rejection is respectfully requested.

III. The Rejection Under 35 U.S.C. § 112, First Paragraph, Written Description

The Examiner has rejected claims 1 and 3 under 35 U.S.C. § 112, first paragraph, for allegedly lacking an adequate written description. Final Action at pages 22-23; Examiner's Answer at pages 10-11.

The Board did not find this issue ripe for review at that time the Decision issued and declined to reach the merits of this rejection. Decision at page 33. The Decision advises that if prosecution of this case is reopened, Applicants and the Examiner should consider the issue in light of the "Guidelines for Examination of Patent Applications under 35 U.S.C. § 112, ¶ 1 'Written Description' Requirement", 66 Fed. Reg. 1099 (January 5, 2001) and in light of the Federal Circuit decision in *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 296 F.2d 1316, 63 U.S.P.Q.2d 1609 (Fed. Cir. 2002). Applicants herein reiterate the statement made in footnote 1, *supra*. In particular, Applicants note that these Written Description Guidelines are not binding on Applicants. *See, e.g., Enzo Biochem,* 323 F.3d at 964 ("[t]he Guidelines, like the Manual of Patent Examining Procedure ("MPEP"), are not binding on this court, but may be given judicial notice to the extent they do not conflict with the statute.") Nonetheless, Applicants herein consider the most recent Written Description Guidelines in the present analysis. In view of these statements, Applicants readdress the issue below.

Applicants believe the only remaining issue under 35 U.S.C. § 112, first paragraph, is whether Applicants have sufficiently described in the present specification the genus of nucleic

acid molecules described by claim 1 comprising SEQ ID No. 1 or its complete complement. With regard to claim 2, applicants note that the Examiner has admitted that a nucleic acid molecule consisting of SEQ ID No: 1 meets the written description requirement. *See* Advisory Action at page 19.

According to the Examiner, Applicants allegedly fail to satisfy the written description requirement because the nucleic acid molecules of claim 1 are allegedly "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s)...had possession of the claimed invention." Final Action at page 21; Advisory Action mailed November 22, 2000 ("Advisory Action"), at page 10. The bases for this challenge are that (1) claim 1 would allegedly cover "an astronomically large genus of nucleic acid molecules comprising SEQ ID NO: 1" and (2) the "disclosure of the single nucleic acid molecule set forth as SEQ ID NO: 1 does not adequately describe the astronomically large number of possible nucleic acid molecules embraced [by the claims]." Advisory Action at page 10, *see also* Final Action at pages 22-23. These are not proper bases for a written description rejection of a "comprising" claim. If they were, every "comprising" claim ever written would be invalid for failing to describe every nuance of the claimed invention.

Applicants have provided an adequate description of the claimed nucleic acid molecules that demonstrates to one skilled in the art that Applicants had possession of the claimed invention. Indeed, the Examiner agrees with Applicants that the specification provides an adequate written description of a nucleic acid molecule of claim 2, *i.e.*, nucleic acid molecules consisting of SEQ ID No. 1, and therefore that Applicants are in possession of those nucleic acid molecules. Final Action at page 22. Furthermore, the Examiner has also acknowledged that Applicants have possession of, and have adequately described, vectors comprising SEQ ID No. 1. *Id.* The Final Action apparently failed to note that these vectors comprising SEQ ID No. 1 are in fact nucleic acid molecules of claim 1 because the vectors "comprise" SEQ ID No. 1.[11]

[11] The Examiner appears to waiver in this position. The Advisory Action states "[t]his genus is not restricted to any particular disclosed subgenus or species, such as vectors comprising SEQ ID NO: 1 as an insert. The only nucleic

Therefore, the nucleic acid molecules of claim 1 are adequately described under 35 U.S.C. § 112, and the rejection must be withdrawn as improper.

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description requirement has been met. *In re Alton*, 76 F.3d at 1175. A person of ordinary skill in the art would, after reading the present specification, understand that Applicants had possession of SEQ ID No. 1, and therefore, the claimed invention.

Nor was this standard altered by the recent decision of the Federal Circuit in *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 296 F.2d 1316, 63 U.S.P.Q.2d 1609 (Fed. Cir. 2002) (reprinted at 323 F.3d 956 (Fed. Cir. 2002); or the Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement; 66 Fed. Reg. 1099 *et seq.* ("Written Description Guidelines"). To the contrary, the holding in *Enzo Biochem* emphasized that "[c]ompliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.' " *Enzo Biochem,* 323 F.3d at 963. More recently, however, the Federal Circuit has expressed that the written description requirement does not require that Applicants recite "the precise 'structure, formula, chemical name, or physical properties' required by *Lilly.*" *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1320, 66 U.S.P.Q.2d 1429, 1438 (Fed. Cir. 2003), *rehearing denied* (Apr.

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acid molecules described by complete structure are the one consisting of SEQ ID NO: 1" Advisory Action at page 53. However, what the Examiner fails to recognize is that such a description still complies with the requirements of 35 U.S.C. § 112, first paragraph. "In its Guidelines, the PTO has determined that the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... *i.e.*, complete or partial structure, other physical and/or chemical properties...' ". *Enzo Biochem,* 323 F.3d at 964.

25, 2003); *Petition for Certiorari Filed,* 72 U.S.L.W. 3106 (Jul. 24, 2003) (NO. 03-124). Rather, *Moba* reemphasized that "[t]he test for compliance with § 112 has always required sufficient information in the original disclosure to show that the inventor possessed the invention at the time of the original filing. . . [t]he written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. . . ' " *Moba,* 352 F.3d at 1320-1321, *quoting Union Oil Co. of Cal. v. Atlantic Richfield Co.,* 208 F.3d 989, 997, 54 U.S.P.Q.2d 1227, 1232 (Fed. Cir. 2000).

Applicants have provided the nucleotide sequence required by the claims, *i.e.*, SEQ ID No. 1, and have thus established possession of the claimed invention. The fact that the claims at issue are intended to cover molecules that include the recited sequences joined with additional sequences does not mean that Applicants were any less in possession of the claimed nucleic acid molecules. It is well-established that use of the transitional term "comprising" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986).

Furthermore, the present application describes more than just the nucleotide sequence required by the claims (SEQ ID No. 1), for example, it describes vectors comprising the claimed nucleic acid molecules (specification at page 47, line 14 through page 54, line 14), and not only describes, but also associates with it a deposit, *i.e.*, the clone from which SEQ ID No. 1 was sequenced (designated "LIB3049-003-Q1-E1-H7).[12] *See* Sequence Listing at page 1; Applicants' Third Response dated September 13, 2000, at page 1; La Rosa Declaration under 37 C.F.R. § 1.132, dated September 11, 2000, at ¶ 3. Furthermore, the addition of extra nucleotides

[12] Applicants respectfully point out that the *Enzo Biochem* Court recognized the written description may be satisfied by the deposit of biological material. *See Enzo Biochem,* 323 F.3d at 966 ("because the deposited sequences are described by virtue of a reference to their having been deposited, it may well be that various subsequences, mutations, and mixtures of those sequences are also described to one of skill in the art.")

or detectable labels to the nucleotide sequence of SEQ ID No. 1, for example, is readily envisioned by one of ordinary skill in the art upon reading the present specification,[13] in particular at page 16, lines 1-10 (describing sequences with labels to facilitate detection), page 21, lines 1-9 (describing fusion nucleic acid molecules), page 25, lines 1-19 (describing automated nucleic acid synthesizers that can be used to build nucleic acid molecules), and page 66, line 25 through page 67, line 6 (citing references describing the construction, manipulation and isolation of nucleic acid macromolecules).

The Examiner asserts that ""[t]he specification fails to provide any structural or functional characteristics for these desired nucleic acid molecules. . . that would distinguish them from the other members of the genus". Examiner's Answer at page 55; *see also* Final Action at page 21. The Advisory Action appears to assert that each nucleic acid molecule within the genus must be "described by complete structure." Advisory Action at page 20. These assertions are totally unfounded. An adequate written description of a genus of nucleic acids may be achieved by a "recitation of structural features common to the members of the genus." *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). *See also Enzo Biochem,* 323 F.3d at 969 ("the written description requirement is satisfied by the patentee's disclosure of 'such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.' ")' *quoting Lockwood,* 107 F.3d at 1572. The structural feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non-members.[14] *Regents of the University of California*, 119 F.3d at 1568-69.

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[13] The Advisory Action asserts on one hand that the "specification does not disclose what characteristics these additional sequences may or may not have that are consistent with the operability of the nucleic acid molecules as probes or primers," Advisory Action at page 21, but on the other hand acknowledges that "a range of small nucleic acid sequences are routinely added to nucleic acids to be used as probes or primers." Advisory Action at page 19. Apparently the Advisory Action is arguing that Applicants must teach "conventional and well-known genetic engineering techniques" in direct contravention of established patent jurisprudence. *E.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000).

[14] The Advisory Action confuses the issue by asserting that "the specification provides no physical (i.e. structural) characteristics of [full length mRNAs, cDNAs and genomic sequences comprising SEQ ID No. 1] to distinguish them from other nucleic acid molecules comprising SEQ ID No: 1." Advisory Action at page 21. This assertion has no basis in law. The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids

The Examiner's analysis, if true, would place a greater burden on applications pertaining to biotechnology inventions than is recognized under the law. As expressed in *Moba,* the nucleotide-by-nucleotide recitation of the structure of a biotechnological invention as necessary for satisfying the written description requirement under 35 U.S.C. § 112, first paragraph, has been compared to a "super-enablement" standard. *See Moba,* 1324-1325 (Rader, J., concurring) ("[a] new protein or other DNA-related discovery may contain a chain of hundreds of amino acids. Many of the amino acids in the chain have substitutes that may take their place without altering the functional properties of the protein. Consequently, a 'precise definition' of the new protein, as required by *Lilly,* apparently requires tedious disclosure of thousands of potential permutations of the amino acid sequence that all fall within a proper description of the protein's functions, properties, and DNA source.") This requirement was expressly rejected for software-related inventions and the viability of the "precise definition" rule expressed in *Lilly* has been eroded by the recent decisions *Moba* and *Enzo Biochem.*

Applicants have satisfied the legal requirement for written description. The claimed nucleic acid molecules are a genus of nucleic acid molecules having the common structural feature of SEQ ID No. 1 or its complete complement. This common structural feature is shared by every nucleic acid molecule in the claimed genus, and it distinguishes the members of the claimed genus from non-members. If a nucleic acid molecule such as an mRNA contains SEQ ID No. 1, then it is a member of the claimed genus. If a nucleic acid molecule does not contain SEQ ID No. 1, then it is not a member of the claimed genus. The presence of other nucleotides at either end of the recited sequence will not interfere with the recognition of a claimed nucleic acid molecule as such – it either contains the nucleotides of SEQ ID No. 1, or its complete complement, or it does not.

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may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California* at 1568-69. There is no requirement to distinguish certain members of the claimed genus from other members of the claimed genus.

Thus, claim 1 satisfies the written description requirement. Therefore, the rejection under 35 U.S.C. § 112, first paragraph, is improper. Reconsideration and withdrawal of this rejection is respectfully requested.

Conclusion

In view of the foregoing arguments and amendments, each of the presently pending claims is believed to be in immediate condition for allowance. All of the stated grounds of rejection have been traversed, accommodated, or rendered moot. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. The Examiner is encouraged to contact the undersigned at 202.942.5000 should any additional information be necessary for allowance.

Respectfully submitted,

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